Coaching Alternative Parenting Strategies (CAPS) Study: Targeting Neurobiological and Behavioral Mechanisms of Self-regulation in High-risk Families

NCT #02684903

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CAPS Study Protocol

Screening Procedures

This randomized controlled trial received ethics approval from the University of Oregon Institutional Review Board as well as the State of Oregon's Department of Health and Human Services. A DHHS certificate of confidentiality was obtained to further protect the identity of research subjects in the study. Parents and guardians provided written informed consent to participate, and children gave verbal assent prior to engaging in any study procedures.

Eligible families were identified and recruited to participate in the clinical trial through the Department of Human Services (DHS) Child Welfare and Self Sufficiency divisions. DHS staff members identified eligible families from their database if the primary caregiver had 1) no history of perpetrating sexual abuse and 2) a child between 3 and 8 years old. Following this pre-selection process within DHS, a core member of the CAPS research team contacted each family to invite them to participate in the study and further screen them for eligibility. Families were free to participate or decline and were informed that they would be randomized to either the PCIT intervention or would be provided services as usual after completion of their baseline assessment. Interested families were screened for eligibility on the following criteria: (a) the participating parent was at least 18+ years old at study entry and (b) is the participating child's biological or custodial parent; (c) the participating child was between 3 and 7 years old at study entry; (d) no parent or caregiver in the home was a documented child sexual abuse perpetrator per child welfare records, (e) the parent spoke sufficient English to engage in the assessment, and (f) the parent provided written informed consent to participate.

Clinical Trial Design

Two assessments were completed for all study families (pre-treatment and post-treatment), and a mid-treatment assessment was completed for PCIT families only. Each of the pre- and post-treatment assessments consisted of two separate visits that were scheduled approximately one week apart. Following completion of both visits in the pre-treatment assessment, families were randomly assigned to one of two conditions in this parallel groups design: PCIT treatment or Family Services-as-Usual (SAU) control. Families were overallocated to the intervention condition at a rate of 1.5:1 to ensure an ample number of families accessed the intervention. Random assignment to condition was retained through the overallocation process. Allocation was concealed from research assistants who collected data at all assessment waves.

Pre-treatment assessments were conducted on enrolling families from spring, 2016 through spring, 2019. Mid-treatment and post-treatment assessments were conducted through March, 2020, and ceased due to the COVID-19 pandemic shutdown. Families randomized to PCIT complete post-treatment immediately after their last PCIT session, or approximately 9–12 months after study entry for those who discontinued PCIT prematurely.

Families randomized to SAU control complete post-treatment approximately 9–12 months after study entry. Post-treatment assessments for the SAU control families were case control matched with the PCIT group on time from study entry to post-treatment assessments.

Assessment Procedures

Pre-treatment and post-treatment assessments were conducted with all participants in the study, each completed in two successive laboratory visits scheduled one week apart. Mid-treatment assessments were conducted only with PCIT intervention families, after completion of the first PCIT phase (i.e., child-directed interaction, CDI) and before beginning the second PCIT phase (i.e., parent-directed interaction, PDI). Mid-treatment assessments were completed in one laboratory visit. Pre-treatment, mid-treatment, and post-treatment assessments each included joint parent-child tasks, individual child tasks, and individual parent tasks. Cardiac physiology was monitored at rest, with participants watching a neutral video either jointly before parent-child tasks or individually before solo tasks. Cardiac physiology was also measured during all experimental tasks and during recovery periods (where participants again watch a neutral video) immediately following each task (see physiology acquisition details in *Outcome Measures* below). Parents were compensated for their time at each visit, offered paid taxi services or reimbursed for transportation, and children were given a small prize. Detected child maltreatment outcomes will be evaluated using the state-wide child welfare administrative database, with matches based on unique identifiers for the participating child and individual unique identifiers for the participating parent. All database matches will be manually checked to confirm any positive matches for future maltreatment reports where the participating study parent is identified as the perpetrator. Any reports made by study therapists will be considered “surveillance effect” reports and treated appropriately in data analyses.

Pre- and Post-Treatment Assessment

Following voluntary informed consent procedures, parents and children completed anthropometric measures (i.e., standing height, weight, and waist circumference) and were fitted with seven disposable, pre-gelled electrodes for the recording of electrocardiogram (ECG) and impedance cardiogram (ICG). ECG was measured from three electrodes placed in a modified Lead II arrangement on the distal right clavicle, lower left rib, and lower right abdomen. ICG was measured from two electrodes placed on the participant’s midline along the top end of the sternum between the two clavicles, at the bottom end of the sternum where the ribs meet, and two electrodes along the spine. ECG and ICG data were wirelessly transmitted *via* an ambulatory impedance cardiograph (Mindware Mobile #50-2303-00; Mindware Technologies, Westerville, OH, USA) to a desktop computer equipped with Mindware’s Biolab (2.4) acquisition software that integrates simultaneously recorded audio and video. Both parents and children wore a vest throughout each visit that secures the wireless ambulatory monitor close to their body and allowed them to move freely during the tasks. Cardiac physiology was monitored throughout all tasks at each visit for both parents and children. After children and parents were fitted with the electrodes, a 3-min resting baseline measure of parent and child’s concurrent cardiac physiology was obtained while they were sitting quietly together and watching a neutral video of oceanic animals. Immediately afterward, systolic and diastolic blood pressure, and resting pulse were assessed *via* blood pressure cuffs, while the parent and child remained sitting.

Following assessment of initial resting cardiac physiology, dyads completed two joint interaction tasks that were video- recorded and during which cardiac physiology was collected.

First, the standard PCIT Dyadic Assessment Protocol (33) employed a standard set and arrangement of toys that were spread out on the playroom floor for all dyads. Parents were provided with an earbud and walkie-talkie to allow assessors to provide task instructions while parents were alone in the playroom with their child. The PCIT dyadic assessment protocol consists of three 5-min parent-child interactions: a 5-min Child-Led Play task (i.e., *please follow your child's lead*…); followed by a 5-min Parent-Led Play task (i.e., *now you decide on what you two will play*…), and a 5-min Clean-Up task (i.e., *it's time for your child to clean up all of the toys*). After the interaction, the parent's earbud was removed, and cardiac physiology was assessed during a 2-min joint recovery before the dyad began the second interaction task. Dyads then completed the Social Engagement task (SET) during which the child and adult are seated in close physical proximity while completing three reciprocal activities: (1) gently pointing to the other's facial features (i.e., hair, chin, nose, and ears); (2) counting each other's fingers; and (3) whispering a story in each other's ear. Children completed the task twice: once with their parent and once with a female research assistant. Each activity was presented for a fixed time interval and the story told by the research assistant was the same with all families. Activity order remained consistent across dyads, whereas the interactive partner condition (i.e., parent or research assistant) was counterbalanced within assessment wave. That is, children were randomly assigned to a partner order that remained constant throughout subsequent assessment waves. Cardiac physiology was assessed in another 2-min joint recovery immediately after completing the SET, and then, blood pressure readings were obtained. Parents and children were given a short break and small snack prior to transitioning into individual tasks.

Parents were taken to a separate testing room in the lab, where the Mindware Mobile carrier was removed and replaced with Biopac carriers for ECG and ICG [Dual Wireless Respiration and ECG BioNomadix Transmitter (BN-Tx); Biopac Systems, Inc.]. Next, parents were fitted with a 256-channel high density Electrical Geodesics Inc. (EGI Philips; Eugene, OR) Hydrocel Geodesic Sensor Net while their child observed. EEG was recorded at a sampling rate of 500 Hz using the EGI net and Net Amp 300 amplifier integrated with Net Station software version 5.2.0.2 (EGI Philips; Eugene, OR). Parents completed a 4-min resting EEG task in which they first closed their eyes for 2 min and then fixated on a blank screen for 2 min while seated in a dark room. Next, a 3-min resting baseline measure of cardiac physiology was collected while parents and children watched a neutral ocean video. Parents completed the executive function tasks [Auditory Attention (AUDAT) and Stop Signal; specified in *Outcome Measures* below] while simultaneous EEG and cardiac physiology were recorded. Parents completed an Emotional Go/No-Go task to conclude visit #1. Meanwhile, children completed two subtests of the Woodcock Johnson-III Tests of Achievement and two brief self-regulatory tasks [Head-Toes-Knees-Shoulders (HTKS); Working Memory] while cardiac physiology was monitored during each task and for 2- min recovery periods after each task. Note that children's cardiac physiology was recorded during an additional 2-min standing baseline prior to the HTKS task.

Families returned to the lab for a second 2-hour visit within one week of their initial visit. During visit #2, children were fitted with a 64-channel EGI Hydrocel Geodesic Sensor with identical EEG equipment and acquisition software to that used with parents. Children completed executive functioning tasks (AUDAT and Zoo Go/No-Go) while simultaneous EEG and cardiac physiology were recorded. Children then completed the Emotional Go/No-Go task while cardiac physiology was recorded. During this time, parents completed questionnaires that allow for the assessment of socio-demographic characteristics, environmental risk, and child behavior (see *Outcome Measures*). After parents and children both completed individual tasks, peak

expiratory flow (i.e., cardiovascular function) was measured using a spirometer, and the highest of three values was recorded within-person. Next, whole blood spots were collected from both parents and children to assess intervention effects on metabolic and immune markers. Four to five spots of blood (~50 ml each) were collected on Whatman strips, then were dried, processed, and frozen at −20°C, before samples were transferred for storage in a padlocked −80°C freezer to undergo enzyme-linked immunosorbent assays (ELISA). All research assistants responsible for collecting blood spots first completed a comprehensive Bloodborne Pathogens training that outlined emergency procedures, safe handling, contact risks, and exposure control plan, prior to working with participants. Research assistants used disposable masks that cover the nose and mouth, goggles, and disposable gloves. At the end of the pre-treatment assessment, the parent was given a sealed, double-blind randomization letter after completing questionnaires and prior to collection of allostatic load measures. If the family was randomized to the PCIT treatment condition, a research assistant reviewed the basic structure and goals of PCIT with the parent, gave a brief tour of the PCIT clinical rooms, and scheduled the family for an intake session with an available therapist.

Mid-Treatment Assessment

Only families who were randomized to the PCIT condition and engaged in treatment sessions were invited to complete a mid-treatment assessment. Written informed consent from the parent and verbal assent from the child were obtained. During this single-visit assessment, dyads completed assessment tasks noted above using identical procedures unless specified here. Parent and child provide anthropometric measures (i.e., height, weight, and waist circumference) and then were fitted with seven disposable, pre-gelled electrodes for recording cardiac physiology during a 3-min joint resting baseline. Dyads completed the PCIT Dyadic Assessment Protocol during which cardiac physiology data were collected. Cardiac physiology was recorded during a 2-min recovery. Children then completed the Social Engagement task with their parent only (not a research assistant) during the mid-treatment assessment. Cardiac physiology was collected again during a 2-min post-task recovery. Parents and children took a short snack break and then transitioned to individual tasks. Parents then completed the Stop Signal task, during which only behavioral data was collected (i.e., no EEG or cardiac physiology) due to time constraints. Parents completed a subset of the questionnaires that were presented at pre-treatment. Separately, children completed a 3-min measure of resting cardiac physiology while standing, followed by the HTKS task. Children's cardiac physiology was then recorded during a 2-min recovery. Next, the child completed a sitting 3-min resting baseline, followed by the Zoo Go/No-Go task. Neither children nor parents provided EEG data during the mid-treatment assessment due to time constraints. After completion of individual tasks, whole blood spots and measures of peak expiratory flow were collected from both parents and children.

Outcome Measures

Dyadic Parent-Child Interactions

Video-recorded parenting behaviors and child responses during the standard PCIT Dyadic Assessment Protocol (i.e., child-led play, parent-led play, and clean-up tasks) at pre-treatment, post- treatment, and mid-treatment were collected, transcribed and then coded using the well-validated Dyadic Parent-Child Interaction Coding System, Fourth Edition (55) (DPICS-IV). For

the PCIT intervention group, DPICS-IV coding was also completed on parent-child interactions during Child Directed Interaction (CDI) sessions (i.e., standard, 5-min child-directed play segment) and standard Parent Directed Interaction (PDI) session segments that began with the 5-min child-directed free play segment (see *PCIT Intervention and Delivery* below). PCIT session coding was conducted using only the session video-recordings (i.e., without transcripts). Parenting behaviors that were coded include labeled praises, unlabeled praises, behavior descriptions, and reflections; criticisms, direct and indirect commands, questions, and neutral talks. Children's compliance and non-compliance behaviors in response to parent commands were coded. Commands where children have no opportunity to comply were also coded. Coders completed 20 hours of intensive, hands-on training prior to coding study assessments, and continued to meet regularly to maintain 80% inter-rater reliability. All coders were blind to participants' condition group and assessment wave. Parent and child behaviors were coded sequentially and summed to calculate a task average for each behavior. For assessment visits (i.e., pre-treatment, mid-treatment, and post-treatment), values were also summed in 30-sec epochs within each task and summarized into task averages. Reliability coding was completed on 20% of study families, with criterion set to 80% interrater reliability.

Cardiac Physiology

From ECG/ICG recordings of cardiac physiology, RSA and pre-ejection period (PEP) were assessed as indices of the parasympathetic and sympathetic nervous systems, respectively. RSA is derived from high-frequency heart rate variability measured in the ECG (children, 0.24 to 1.04 Hz; adults, 0.12 to 0.40 Hz). PEP is derived by measuring the distance between the Q-point of the ECG and the B-point of the dZ/dt wave, indexing the time interval between opening of the left ventricle and ejection of blood into the ventricle. Heart rate is evaluated from the ECG as the number of R-R wave intervals per minute. Both RSA and PEP are measured in 30-s epochs, except during the Emotional Go/No- Go task (described below) during which they are assessed for the task duration. All data was cleaned offline using Mindware HRV analysis software version 3.1.1. Data were visually inspected and cleaned for movement artifacts and equipment errors.

Neurophysiology

EEG was acquired from parents and children during rest periods and completion of executive function tasks (i.e., Stop Signal, Go/ No-Go, and AUDAT) during T1 pre-treatment and T3 post-treatment sessions only. EEG was recorded at a sampling rate of 500 Hz using an EGI Hydrocel Geodesic Sensor Net integrated with Net Station software (Electrical Geodesics Inc; Eugene, OR). After recordings were completed, raw EEG files were exported from Net Station in simple binary format to prepare them for preprocessing. After preprocessing, continuous EEG files were epoched into task-specific bins by time-locking EEG to event codes synchronized with events of interest, to yield ERPs for analysis. Each epoch was subjected to standard artifact rejection procedures. Final processed ERP files for a given participant for each task will consist of all artifact-free epochs of interest, relative to a 200-ms pre-stimulus baseline. Grand averages are created for each task by averaging across groups of participants.

Attentional Control

Parents and children individually complete the Auditory Attention Task (AUDAT) to assess

attentional control. Participants listen to one of two children's stories presented simultaneously in separate free-field speakers situated 90° to their left and right sides. During each story, one speaker presented a male voice while the other speaker presented a female voice, each reading different narratives ranging from 2.5 to 3.5 min in length and edited to remove pauses greater than 1 second. An arrow on the screen reminded the participant which story to attend to. Selective attention during the task is assessed *via* ERPs recorded to 100-ms sound probes (i.e., ba, buzz sounds) superimposed on the to-be-attended and unattended stories. Each participant attends to four separate stories over the duration of the task, with direction of attention counterbalanced across gender of narrator (male or female) and side of speaker (left or right) with a pseudo-randomized order. Immediately after each story, the participant was asked three comprehension questions to ensure they were attending to the appropriate narrative.

Inhibitory Control

Parents complete two 6-min blocks of the Stop Signal task to assess response inhibition and impulse control. A stop-signal response time (SSRT) was calculated as the difference between the speed of the stop process and the stop signal delay, reflecting efficiency of the inhibitory control process. Each block of the task consists of 128 trials (32 stop trials) and lasted 6 min. Total testing time was approximately 12 min for 256 trials. Of interest were ERPs time-locked to the stop signal and ERPs time-locked to responses, for example, N2 and P3 ERP components shown to be enhanced in amplitude on trials that are correctly inhibited.

Participating children completed four 2.5-min blocks of a Zoo Go/No-Go task to measure inhibitory control. Children were presented with a story of a zookeeper and instructed to respond by pressing on a button box each time a zoo animal appears on the computer monitor (go signal). After 12 practice trials, they are told to withhold their response each time they see a monkey. On No-Go trials (i.e., monkey stimulus), children were given feedback for their responses, with a smiley emoticon for correct responses and correctly withheld responses, and an angry emoticon for incorrect responses (i.e., did not withhold or did not respond). After a brief practice period that includes the monkey and emoticon feedback, children complete four blocks of 45 trials each, with short breaks in between blocks, for a total of 180 trials. Of these, 33% of trials per block are no- go trials. Children also completed the Head Toes Knees Shoulders task (HTKS), adapted for use with ages 4–8, to assess behavioral response inhibition, and with McClelland's modifications, is appropriate for use with children aged 3 to 7 years. Children are introduced to four instructions, "touch your head," "touch your toes," "touch your shoulders," and "touch your knees." After a series of non-conflict trials in which they do as instructed, children were told to respond using the "opposite" rule to the examiner (e.g., touch head when examiner says touch toes). A total of 30 trials were presented, with responses scored as correct, self-corrected, or incorrect.

Emotion Regulation

Parents and children also complete Emotional Go/No-Go tasks to assess emotion regulation. Stimuli were images of neutral, angry, happy, sad, and fearful facial expressions for parents, and only neutral, happy, or angry for children. Parents and children each completed an age-appropriate version of the task, in which they were instructed to press a response key when a target emotion was presented, and to refrain from responding when a distractor

emotion was presented.

Survey Measures

Parents are asked to report on both their own and their child's adverse life experiences, attributions, socio-emotional functioning, general health, and relationships. In addition, parents report on their parenting stress, children's trauma symptoms and children's behavior. All questionnaires are completed in interview format with a trained research assistant. Parents are given a small booklet of scales for Likert-type questions, which they can point to when responding. Responses are entered into Qualtrics by the research assistant and automatically scored. Table 1 includes a list of survey measures.

PCIT Intervention and Delivery

PCIT is an intensive, behavioral parent-training intervention model grounded in social learning, attachment, and family systems theories that uses live skills coaching of parent-child interactions. Families were scheduled for PCIT sessions in the morning, afternoon, and evening on weekdays and on weekends per family preferences. During sessions, parents wear a small earpiece while the therapist coaches *via* a headset from the other side of a one- way mirror, providing positive feedback, support, and guidance. Each session was 50–60 min long. The PCIT intervention is assessment-driven and includeed weekly DPICS coding of parent skills mastery at the beginning of each PCIT session to guide the coaching focus, and parent ratings of child behavior problems using the Eyberg Child Behavior Inventory (ECBI). (See PCIT International guidelines). Parents in the intervention condition were invited to complete a second optional informed consent if they wished for their PCIT therapist to provide a routine progress report to their DHS caseworker. No additional study data, aside from the optional progress reports and any mandated maltreatment reporting, was shared with DHS authorities. Families were provided light snacks at each visit and reimbursed for transportation costs to attend sessions. Treatment was suspended or discontinued if the child was removed from the home entirely during the course of treatment; however, families were retained in the study through the T3 post-treatment assessments when possible.

Interventionist Training and Fidelity

A team of eight masters or Ph.D. level practitioners completed an intensive 40-hours training with Dr. Funderburk and her clinical team of nationally certified PCIT trainers at Oklahoma University Health Sciences Center (OUHSC) and delivered the PCIT intervention to CAPS study families. PCIT therapist training conformed to PCIT International standards for observed case practice and intervention fidelity criteria. Study therapists received ongoing weekly consultation from Master and Level II Trainers at OUHSC, in addition to live, video-based consultation during conduct of their PCIT sessions with study families. Adherence to the protocols was assessed using live, remote, direct observation of sessions and by completing session-by-session fidelity checklists following each session. All PCIT sessions were videotaped to ensure rigorous adherence to the PCIT protocol and a minimum of 10% of videotaped sessions wereoded for fidelity by independent observers blind to family outcomes at 90% criterion.

Services-as-Usual-Control Condition

The Services-as-Usual (SAU) control condition was an ecologically valid, ethical comparison group in which families receive typical services provided by child welfare agencies, including access to a variety of in-home family visitation services, respite childcare, and other individual child counseling and/or parent education training. Parents completed a Services Utilization Questionnaire *via* interview at post-treatment, indicating how many times in the past 6 months anyone in the family received support from a wide range of social services. Thus, services utilization was tracked *via* parent self-report at T3 post-treatment for all study families.